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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,776

08/18/2003

Swapan Roy

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

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1639

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DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/642,776	Applicant(s) ROY ET AL.	
	Examiner CHRISTOPHER M. GROSS	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Responsive to communications entered 1/25/2008. Claims 1-36 are pending. Claims 19-36 are withdrawn. Claims 1-18 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

This application claims benefit of provisional application 60/403,747 filed 08/16/2002.

Election/Restrictions

Applicant's election without traverse of "silica surface" for the species of support of claim 5 in the reply filed on 1/25/2008 is acknowledged.

Applicant's election without traverse of "succinyl group" for the species of specificity-determining ligand of claim 2 in the reply filed on 1/25/2008 is acknowledged.

Applicant's election **with traverse** of:

$\text{-CH(OH)CH}_2\text{CH}_2\text{O(CH}_2\text{)}_m\text{OCH}_2\text{CH}_2\text{CH(OH)-}$

for the species of spacer of claim 4 is acknowledged

The traversal is on the ground(s), see p 15-16 of remarks entered 1/25/2008, that the guidelines in the MPEP 809.02(a) are in conflict with 35 USC 121, 35 USC 2(2)(A) and 37 CFR 1.142(a). In particular, applicant points out that said statute and rules provide for only restriction of a **claimed** invention, whereas the MPEP 809.02(a) provides for restriction of **disclosed** (as only found in the specification) species.

In this regard, the following is noted. (i) 35 USC 121 governs independent and distinct *inventions*, rather than *species*. (ii) The spacer genus set forth claim 4

encompasses multiple species, thus spacer species are indeed claimed, albeit indirectly. Therefore, the examiner submits that MPEP 809.02(a) is in harmony with statute and rule since the MPEP guidelines concern species rather than separate inventions. Assuming arguendo a distinction between inventions and species can not be made in the statute and rules, the examiner further submits species are implicitly claimed.

The requirement is still deemed proper and is therefore made FINAL

Withdrawn Objection(s) and/or Rejection(s)

The rejection of claims 1-5,7-15,17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 4 and 13 under 35 U.S.C. 102(b) as being anticipated by Keyes (US Patent 4,714,676) is hereby withdrawn in view of applicant's amendments to the claims.

Maintained Claim Rejection(s) - 35 USC § 112

Claims 6 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 15 each recite the limitation 'a predetermined maximum content' yet the specification lacks a clear definition as to the meaning of predetermined.

As such the metes and bounds of claims 6 and 15 are deemed indefinite.

Response to Arguments

Applicant argues, see p 17 third paragraph (1/25/2008), that paragraph 0080 of the instant specification provides an extensive definition of the phrase predetermined solids content.

Paragraph 0080 is reproduced below:

The inventors, while not wishing to be bound by theory or hypothesis, have designed very low density specificity-determining substrates with an open architecture. This is intended to overcome perceived problems such as site-site interactions between bound protein solutes, and nonspecific binding. **This objective is accomplished in the present invention by having a solids content of the support, when equilibrated with an ambient fluid, less than a predetermined maximum content.** In certain embodiments, including those in which the support is not a solid surface, the predetermined maximum solids content may be less than about 12% w/v, or less than about 10% w/v, or less than about 8% w/v, or less than about 7% w/v, or less than about 6% w/v, or less than about 5% w/v, or less than about 4% w/v, or less than about 3% w/v, or less than about 2% w/v, or less than about 1% w/v.

Emphasis Added.

The above passage is confusing in that it is not clear what 'v' in % w/v is referring to, especially in view of p 20 of applicants remarks entered 1/25/2008 last three lines, which mentions the 'solids content of the specificity-determining substrate' differs from a 'suspension of the specificity-determining substrate' in that the latter clearly includes fluid in excess of the volume contained within the bounds of a particle.

Assuming *arguendo* that 'w' refers to the solid support (i.e. weight) and 'v' refers to the ambient fluid in equilibrium (i.e. volume), it is noted that exclusion of fluid in excess of the volume contained within the bounds of the particle is *not recited in paragraph 0080 nor the rejected claims*.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a solids content measurement *excluding* fluid in excess of the volume contained within the bounds of a particle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Maintained Claim Rejection(s) - 35 USC § 102

Claims 1-3,5-6,10-12,14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Keyes (US Patent 4,714,676).

Response to Arguments

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

First, applicant argues see p 19 lines 1-3 (1/25/2008) Keyes do not teach the specificity-determining substrate reversibly forms a complex with a protein molecule that is suitable for proteomic separations and wherein the spatial separation between

adjacent ligand groups is greater than a predetermined minimum distance of 5 angstroms, as set forth in claim 1.

In response to applicant's arguments, the recitation "reversibly" and "suitable for proteomic separations" in amended claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that Keyes does not teach a complex "suitable for proteomic separations", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In so far as the limitation "a spatial separation between adjacent ligand groups is greater than a predetermined minimum distance of 5 angstroms" is concerned, applicant's attention is respectfully invited to column 8 line 50 of Keyes which indicates succinic anhydride reacts with free amine groups on proteins. Keyes teaches in column 7, lines 19-20 an embodiment entailing Bovine Serum Albumin. Solely to rebut applicant's argument, data provided by Huang et al (2004 J. Am. Soc. Mass Spectrom. 15: 1237-1247) in figures 1 and 2 indicate that said free amine groups in BSA are

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greater than 5 angstroms apart. Therefore, absent evidence to the contrary, the examiner submits said succinyl groups attached to said free amines of Keyes are similarly greater than 5 angstroms apart, as set forth in amended claim 1.

Second, applicant argues see p 18 third paragraph last two lines and p 19 lines 7-9 (1/25/2008) Keyes do not teach a specificity-determining substrate reversibly bound to protein molecule such as set forth in claim 10. Applicant asserts that Keyes teaches irreversible immobilization.

In this regard, applicant's attention is respectfully invited to column 8 lines 51-55 which indicates that the negatively charged succinylated proteins are electrostatically attached to positively charged surfaces such as ceramic oxide at low pH.

This is not found persuasive because the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") (see MPEP 2145 I.) In the instant case, Applicant's counsel argues that the electrostatic protein immobilization of Keyes is irreversible.

Claims 1-6,8-9,10-15,17-18 rejected under 35 U.S.C. 102(b) as being anticipated by Comb et al (US Patent 5,843,247).

Applicant notes see p 19, last paragraph lines 4-6 that figure 28 of Comb et al does not show a chitin column for purifying proteins as mentioned in the last office

action. The correct figure should have been no. 32. The examiner regrets any confusion that may have arisen.

Response to Arguments

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

First, applicant argues see p 19 last paragraph lines 1-3 (1/25/2008), Comb et al do not teach the specificity-determining substrate reversibly forms a complex with a protein molecule that is suitable for proteomic separations and wherein the spatial separation between adjacent ligand groups is greater than a predetermined minimum distance of 5 angstroms, as set forth in claim 1.

In response to applicant's arguments, the recitation "reversibly" and "suitable for proteomic separations" in amended claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that Comb et al do not teach a complex "suitable for proteomic separations", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In so far as the limitation “a spatial separation between adjacent ligand groups is greater than a predetermined minimum distance of 5 angstroms” is concerned, solely to rebut applicant’s argument, data provided by Hayashida et al (2003 J. Molec. Biol 334:551-565) in figure 3 indicates that each chitin binding site in a chitin binding protein, such as presented by Comb et al are greater than 5 angstroms apart. The examiner submits, absent evidence to the contrary, that the chitin binding domain of Comb et al would similarly bind chitin molecules greater than 5 angstroms apart on a column.

Second applicant argues, see p 19 last paragraph last two lines through the first four lines on p 20 (1/25/2008), that Comb et al do not teach a specificity-determining substrate that reversibly forms a complex with a native protein, asserting that Comb et al teach a method only applicable toward fusion proteins.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., native proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Maintained Claim Rejection(s) - 35 USC § 103

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Comb et al** (US Patent 5834247) in view of **Margel** (US Patent 4732811)

Response to Arguments

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Specifically, Applicant argues, see p 21 first line (1/25/2008) that the suspension (slurry) of Margel et al includes fluid in excess of the volume within the bounds of the particle.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a solids content measurement *excluding* fluid in excess of the volume contained within the bounds of a particle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns "new matter."

This rejection is necessitated by Applicant's amendment to the claims.

Claim 1 has been amended to insert the limitation concerning a specificity-determining substrate that reversibly forms a complex with a protein molecule.

On p 16 second paragraph under 'Amendments to the Claims in the remarks entered 1/25/2008, applicant points to p 3 second paragraph, p 11 fourth paragraph and the examples as passages providing support.

In this regard it is noted, said passages are limited to elution of a protein which is not denatured or inactivated yet does not discuss reversible binding in general. The examiner submits that reversible protein binding may entail elution of *inactive* proteins, as evidenced by paragraph 0185 of US Patent Application 2005/0164339, which discusses His6 tagged proteins eluted under denaturing conditions.

The examiner therefore submits that inadequate support exist for a specificity-determining substrate that reversibly forms a complex in the disclosure as filed.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a

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claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/Mark L. Shibuya, Ph.D./
Primary Examiner, Art Unit 1639